Remarks

I. The Office Action

The April 24, 2006 non-Final Office Action (the "Office Action") in this application:

1.) rejected claims 1-7 and 10-22 on the grounds of nonstatutory obviousness-type double patenting:

2.) rejected claims 1-4, 7, 17 and 20 under 35 U.C.S. 102(b); and

3.) rejected claims 1-7, 12-16 and 20 under 35 U.S.C. 102(b).

Applicant responds as follows.

II. Rejection of claims 1-7 and 10-22 on the grounds of nonstatutory obviousness-type double patenting

The Office Action rejected claims 1-7 and 10-22 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent 6,921,538.

Applicant hereby submits a terminal disclaimer (attached) to overcome the Office Actions nonstatutory obviousness-type double patenting rejection.

Thus, the rejection should be withdrawn.

III. Rejection of claims 1-4, 7, 17 and 20 under 35 U.S.C. 102 (b)

The Office Action rejected claims 1-4, 7, 17 and 20 under 35 U.S.C. 102 (b) as being anticipated by Micheli et al. (1998) ("Micheli") . Applicant traverses the rejection.

Briefly, and taken as a whole, Micheli reports a finding of correlative onset of hemifacial spasm, a movement disorder, in an elderly male having a history of coronary artery disease, with the use of sublingual isosorbide dinitrate to ameliorate chest pain. Micheli reports that hemifacial spasm, in general, is attributable to vascular compression at the facial pontine root entry zone. It is disclosed that the patient had been treated with botulinum toxin to treat the hemifacial spasm. As is well known, hemifacial spasm is treated by injecting the spasmodic muscles (see e.g. pp. 177-178 in Kemp, L. and Reich, S. "Hemifacial Spasm" in *Current Treatment Options in Neurology* 2004; 6 (3): 175-79). Clearly an intramuscular injection of a botulinum toxin does not teach injecting a botulinum toxin into a lower brain region or a pontine region, to which all the present claims are limited.

Micheli simply discloses the onset of a hemifacial spasm, which is well known to be a neuromuscular disorder, not a neuropsychiatric disorder. All claims are limited to treatment of a neuropsychiatric disorder

Thus, the rejection should be withdrawn.

IV. Rejection of claims 1-7, 12-16 and 20 under 35 U.S.C. 102 (b)

The Office Action rejected claims 1-7, 12-16 and 20 under 35 U.S.C. 102(b) as being anticipated by Auchus et al. ("Auchus"). Applicant traverses the rejection.

Auchus discloses the injection of botulinum toxin into the hypertrophied left sternocleidomastoid, left scalenus, left splenius capitis and left trapezius muscles of a patient suffering Alzheimer's disease. The botulinum toxin is injected to treat cervical dystonia in the patient. Thus, Auchus only discloses botulinum toxin injection into certain neck muscles.

Nowhere in Auchus is local administration to any brain region. All claims are limited to administration of a botulinum toxin to particular brain regions.

Since Auchus does not teach administration of a botulinum toxin to any region of the brain, Auchus cannot anticipate the claims.

Therefore, the rejection should be withdrawn.

V. Conclusion

All issues raised in the final Office Action have been addressed. Examination and allowance of claims 1-7 and 10-22 is requested.

The Commissioner is hereby authorized to charge any fees required or necessary for the filing, processing or entering of this paper or any of the enclosed papers, including the Terminal Disclaimer fee under 37 CFR 1.20(d) and to refund any overpayment, to deposit account 01-0885.

Respectfully submitted,

/Claude L. Nassif/

Date: October 4, 2006 Claude L. Nassif, Reg. No. 52,061

Attached: Terminal Disclaimer
Current Treatment Options in Neurology 2004; 6 (3): 175-79

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